Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 27, 36, 39, 44-46, 70, 72, 92-95 and 103-105 are pending in the application, with claims 27, 39 and 44 being the independent claims. Claims 37, 47 and 100-102 are sought to be cancelled without prejudice to or disclaimer of the subject matter therein. Claims 36, 44, 70, 95 and 103 sought to be amended. New claims 104 and 105 are sought to be added. These changes are believed to introduce no new matter, and their entry is respectfully requested.

A Request for Continued Examination (RCE) is being filed concurrently herewith. Therefore, the finality of the Office Action mailed January 17, 2003 should be withdrawn and this Amendment and Reply should be entered and considered. *See* 37 C.F.R. § 1.114(d).

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

I. Election/Restriction

Claims 100-102 were withdrawn from consideration as allegedly being directed to a non-elected invention. (*See* Paper No. 17, page 2.) Applicants respectfully traverse this restriction requirement for the reasons set forth in the Reply to Restriction Requirement filed on March 19, 2002. Nonetheless, in order to expedite prosecution, claims 100-102 have been cancelled without prejudice to or disclaimer of the subject matter encompassed by these

claims. Applicants reserve the right to pursue claims directed to the subject matter of claims 100-102 in one or more divisional applications.

II. Claim Objection

Claim 70 was objected to for reciting "100-104" because there is no claim 104 pending in the application. (*See* Paper No. 17, page 3.) The claims have been amended to correct any errors in their dependencies. Accordingly, the objection to claim 70 has been fully accommodated and should be withdrawn.

III. Claim Rejections Under 35 U.S.C. § 102

Claims 27, 36, 37, 39, 47, 92-95 and 103 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 2,835,586 ("Peebles") and WO 95/00031 ("Getler"), as evidenced by U.S. Patent No. 6,140,121 ("Ellington"). (*See* Paper No. 17, page 4.) Applicants respectfully traverse this rejection.

An anticipation rejection under 35 USC § 102 requires a showing that each limitation of a claim is found in a single reference, practice, or device. *See In re Donohue*, 766 F.2d 531, 226 USPQ 619, 621 (Fed. Cir. 1985). Claims 37 and 47 have been cancelled solely to expedite prosecution. Claims 27, 36, 39, 92-95 and 103 are directed to agglomerated eukaryotic cell culture medium powders and agglomerated eukaryotic cell culture medium subgroup powders. Since none of the references cited by the Examiner teach or suggest an agglomerated eukaryotic cell culture medium powder or medium subgroup powder, the rejection under § 102 is improper and should be withdrawn.

Peebles refers to methods for the manufacture of dry powdered skim milk. Getler refers to methods for preparing agglomerated milk products and "milk-like" products. Neither reference describes an agglomerated eukaryotic cell culture medium powder or medium subgroup powder.

The Examiner has interpreted the phrases "agglomerated eukaryotic cell culture medium powder," and "agglomerated eukaryotic cell culture medium subgroup powder," as recited in the present claims, as encompassing the powdered skim milk of Peebles and the powdered milk and milk-like products of Getler. (*See* Paper No. 17, pages 5-6.) Applicants respectfully disagree with the Examiner's interpretation of these phrases. Dry powdered milk and milk products are not eukaryotic cell culture media powders or media subgroup powders.

The specification explains that the powdered media and media subgroups of the invention, after being reconstituted in a rehydrating solvent, can be used to cultivate cells. (*See* specification at page 33, lines 9-19, and at page 34, lines 14-20.) In particular, the specification notes that:

> The reconstituted nutritive media, media supplements, media subgroups and buffers *may be used to culture cells* according to standard cell culture techniques which are well-known to one of ordinary skill in the art. In such techniques, the cells to be cultured are contacted with the reconstituted media, media supplement, media subgroup or buffer of the invention under conditions favoring the cultivation of the cells (such as controlled temperature, humidity, lighting and atmospheric conditions).

(Specification at page 34, lines 14-20, emphasis added.) The specification also indicates that the expression "cell culture medium" refers to "a nutritive solution that supports the cultivation and/or growth of cells." (Specification at page 14, lines 5-7.) Thus, the

specification makes it clear that a property possessed by the claimed eukaryotic cell culture medium powders and medium subgroup powders is the ability, when reconstituted, to culture eukaryotic cells.

Dry powdered milk and milk products, when reconstituted, are incapable of supporting the cultivation and/or growth of eukaryotic cells. Culture media and media subgroups contain a complex combination of nutrients, minerals and energy sources that support the cultivation of cells *in vitro*. As stated in the specification:

> Cell culture media provide the nutrients necessary to maintain and grow cells in a controlled, artificial and *in vitro* environment. Characteristics and compositions of the cell culture media vary depending on the particular cellular requirements. Important parameters include osmolality, pH, and nutrient formulations.

(Specification at page 2, lines 3-7.) Some of the considerations that go into the formulation of a culture medium are set forth in the specification at page 14, line 25, through page 15, line 29, and in Allen R. Liss, *Methods for Preparation of Media, Supplements and Substrate for Serum-Free Animal Cell Culture* (cited and incorporated by reference in the specification at page 15, lines 12-14).

A person of ordinary skill in the art would appreciate that milk and milk products do not contain the appropriate components that would permit the cultivation of eukaryotic cells. Thus, dry powdered milk and milk products cannot properly be regarded as cell culture medium powders or medium subgroup powders.

The Examiner presented two arguments to support the interpretation of the phrases "agglomerated eukaryotic cell culture medium powder" and "agglomerated eukaryotic cell culture medium subgroup powder" as encompassing dry powdered milk and milk products. First, the Examiner cited Ellington for the proposition that "[the agglomerated powders of

Peebles and Getler] can be used in the cultivation of eukaryotic cells . . ." (Paper No. 17, pages 5-6.) Ellington, however, does not indicate that milk or milk products can be used to cultivate cells. Ellington simply lists "skim milk" as one of several possible *additional components* that can be included in a culture medium. (*See* Ellington at column 5, lines 29-49.) Ellington does not indicate or suggest that skim milk can support the cultivation or growth of eukaryotic cells, nor does Ellington demonstrate the cultivation of a eukaryotic cell in skim milk. Thus, Ellington does not support the assertion that dry powdered skim milk (or any dry powdered milk product) is a eukaryotic cell culture medium powder or medium subgroup powder.

The second argument put forth by the Examiner apparently relates to statements found in the specification at page 6, lines 13-28 and at page 7. (*See* Paper No. 17, page 6.) According to the Examiner:

> [The agglomerated powders of Peebles and Getler] . . . can be grouped within the scope of the various media subgroupings as described by Applicant on page 6, lines 13-28 and page 7, wherein dried milk can be considered as an animal extract of mammalian cells containing fats, proteins, and vitamins, etc., and whey protein concentrates can be considered as a plant cell.

(Paper No. 17, pages 5-6.) Applicants respectfully disagree with this assertion. Milk is not an extract of a mammalian cell, and whey protein is not derived from plant cells (whey is a protein component derived from milk). Moreover, there is nothing in the specification to suggest that milk or whey can be used as a cell culture medium or medium subgroup. As explained above, milk and milk products, regardless of whether they contain fats, proteins and vitamins, do not contain the appropriate and necessary components that would enable

the cultivation of eukaryotic cells. (*See* specification at page 2, lines 3-7.) Dry powder milk and milk products therefore cannot be regarded as cell culture media powders or media subgroup powders.

Neither Peebles nor Getler teach or suggest an agglomerated eukaryotic cell culture medium powder or medium subgroup powder. Thus, Peebles and Getler cannot and do not anticipate the present claims. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 102 be reconsidered and withdrawn.

IV. Claim Rejections Under 35 U.S.C. § 103

Claims 27, 36, 37, 39, 47, 70, 72, 92-95 and 103 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Peebles and Getler in view of U.S. Patent No. 5,474,931 ("DiSorbo"). (*See* Paper No. 17, page 6.) Applicants respectfully traverse this rejection.

In order to establish a *prima facie* case of obviousness, all the claim elements must be taught or suggested by the cited references. *See In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Claims 37 and 47 have been cancelled solely to expedite prosecution. Claims 27, 36, 39, 70, 72, 92-95 and 103 are directed to agglomerated eukaryotic cell culture medium powders, agglomerated eukaryotic cell culture medium subgroup powders, and kits comprising the claimed medium powders and medium subgroup powders. As discussed in detail above, neither Peebles nor Getler teach or suggest an agglomerated eukaryotic cell culture medium powder or medium subgroup powder. (*See* Section III, above.) Likewise, DiSorbo does not teach or suggest an agglomerated eukaryotic cell culture medium powder or medium subgroup powder. Therefore, the cited references, alone or in combination with

one another, do not teach or suggest all of the elements of the present claims. Accordingly, a *prima facie* case of obviousness cannot be established.

In addition, a *prima facie* case of obviousness requires that there is a suggestion or motivation to combine or modify the cited references. *See In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998). There is nothing in any of the cited references that would have provided a suggestion or a motivation for one of ordinary skill in the art to combine or modify Peebles, Getler and/or DiSorbo. Thus, a *prima facie* case of obviousness cannot be established.

With respect to the issue of a motivation to combine references, the Examiner stated:

> One of ordinary skill in the art would have been motivated to combine the instantly claimed materials in the making of a kit for use in the cultivation of a cell because one would have had a reasonable expectation of success that the making of the claimed kit as a product of sale would be useful and convenient to the biomedical community because DiSorbo relates the reduced cost that his invention provides for the preparation of cell culture media, since the media subgroupings can be easily stored and admixed to make custom media, when needed.

(Paper No. 17, page 8.) Applicants respectfully submit that the Examiner has not provided a legally sufficient showing of a motivation to combine or modify the references. The Examiner has simply cited various asserted advantages of the subject matter of DiSorbo.

The supposed advantages of DiSorbo, however, do not provide a suggestion or motivation to specifically combine the subject matter of DiSorbo with that of either Peebles or Getler. In the context of an obviousness rejection, any asserted showing of combinability of references must be "clear and particular." *See In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). Since no clear and particular evidence has been

presented to demonstrate a motivation to combine DiSorbo with either Peebles or Getler, a *prima facie* case of obviousness cannot be established.

In summary, the cited references do not teach or suggest all of the elements of the present claims, and a person of ordinary skill in the art would have had no motivation to modify or combine the cited references. Applicants therefore respectfully request that the rejection under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Frank R. Cottingham
Attorney for Applicants
Registration No. 50,437

Date: July 17, 2003

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600

Version with markings to show changes made

36. (Thrice amended) The agglomerated eukaryotic cell culture medium powder of [any one of claims] claim 27 [and 100-102], wherein said eukaryotic cell culture medium has a pH of between 7.1-7.5 when said medium is reconstituted with a solvent, wherein said solvent is water or serum.

44. (Thrice amended) [The] An agglomerated eukaryotic cell culture medium supplement powder [of claim 37] prepared by agglomerating a dry powder eukaryotic cell culture medium supplement with a solvent, wherein said dry powder eukaryotic cell culture medium supplement is serum.

70. (Four times amended) A kit for use in the cultivation of a cell, said kit comprising one or more containers wherein a first container contains the powder of any one of claims 27, 36, [37,] 39, 44-46 [47], 92-94 [95] and 103-105 [100-104].

95. (Twice amended) The medium powder of any one of claims [93] 92-94, wherein the non-agglomerated medium powder is a lyophilized or ball-milled powder.

103. (Once amended) The [agglomerrated] agglomerated eukaryotic cell culture medium powder of claim 27 [any one of claims 27, 37, or 39], wherein said solvent is water, serum, aqueous acid or base.

Claims 37, 47 and 100-102 are sought to be cancelled.

New claims 104 and 105 are sought to be added.